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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/154,283	09/16/98	MOD-YOUNG	A CBR-3.0-016

000530 HM12/1106
LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK
600 SOUTH AVENUE WEST
WESTFIELD NJ 07090

EXAMINER

WEBMAN, E

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 11/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/154283

Applicant(s)

M 00 - YOUNG

Examiner

WEBMAN

Group Art Unit

1617

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 7/11/01
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-15, 17-44 is/are pending in the application.
- Of the above claim(s) 22-44 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-15, 17-21 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2 13-15, 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanabe et al in view of Suvisaari et al.

Tanabe et al teach Androgens which are useful in control of male fertility (Abstract). They may be administered alone (column 15 lines 35-36). They have been shown to be useful in male contraception (column 17 lines 54-58). Transdermal delivery injection, and implants are specified (column 17 line 33, column 18 lines 46, 59).

It would have been obvious to use 7-methyl 16-ene nortestosterone as a male contraceptive in view of Tanabe et al.

As to the claimed levels of LH an F/SH as an indication of efficacy, such are well-known in the art (see Suvaari et al abstract).

As to the asserted contradiction in table I of Tanabe et al, applicant has not provided clear and convincing evidence that the data is incorrect. Applicants argue but do not claim doses.

Claims 1-15, 17-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. "Substantially" has no support in the specification

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Claims 1-15, 17-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 “substantially” is vague; it can mean as much as 49% active other than the Androgen.

Applicants argue but do not claim small and ineffective amounts of additional sterilant.

Claims 1, 2, 13-15, 17-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants demonstrate efficacy only for MENT. However, applicants claim efficacy for any Androgen. Applicants argue that they are entitled to a presumptively correct assertion. However, the claimed androgens include testosterone, which applicant stipulates does not lower serum testosterone (page 6 lines 24-27).

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is (703) -308-4432. The examiner can normally be reached on Monday through Friday from 9 AM to 5 PM.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Moezie, can be reached on (703) -308-0570. The fax phone number for the organization where this application or proceeding is assigned is (703) -305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) -308-1235.

Webman/LR

October 10, 2001



EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500